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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,553	11/20/2003	Hans Henrik Ipsen	27554-0009002	3430

26211 7590 10/07/2010
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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
10/07/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/719,553	IPSEN ET AL.	
	Examiner	Art Unit	
	NORA M. ROONEY	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-96* is/are pending in the application.

4a) Of the above claim(s) *44-65 and 74-96* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-43 and 66-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/21/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/21/2010 has been entered.

2. Claims 36- 96 are pending.

3. Claims 44-65 and 74-96 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

4. Claims 36-43 and 66-73 are currently under examination as they read upon a recombinant mutant Bet v 1 allergen and the 'Triple-patch' mutant of species of 'ix.' in claim 37.

5. Applicant's IDS document filed on 06/21/2010 is acknowledged. The crossed out item are not publications with publication dates, but they have been considered.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 36-43 and 66-73 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22, 35, 37-39 and 66-85 of copending Application No. 10/001,245. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims arrive at similar allergenic variants, and by what appears to the Examiner to be the same method of selection, or if not, by an obvious variant thereof. Specifically, Claims 1-22, 35, 37-39 and 66-85 teach a mutant Bet V1

allergen with 1 or more substitutions, wherein said substitutions occur at many amino acid residues that are identical positions between the '245 application and the instant application, such as those recited in copending claim 22 and instant claim 37. Claim 22 of the '245 application recites substituting unspecified amino acids at one or more given positions, whereas the instant application recites specific substitutions at some of the same positions. However, on page 29 of the '245 specification in example 2595, the identical 'triple patch' mutant species of instant claim 37 is disclosed. Therefore, the claims are not patentably distinct from one another for the same reasons as set forth in the Office Action mailed on 05/22/2009.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments submitted on 06/21/2010 have been fully considered, but are not found persuasive.

Applicants argue:

> "Applicants confirm that the '245 application has not issued as a patent. Accordingly, Applicants are not required to respond to the instant rejection at this time.
>
> It is noted that the instant application was filed prior to the '245 application. Thus, according to the rules of practice, if the obviousness-type double patenting rejection is the last remaining rejection in the instant application and rejections remain in the '245 application, the obviousness-type double patenting rejection of the instant claims should be withdrawn and the application permitted to issue as a patent without the filing of a terminal disclaimer. *See* MPEP §804.I.B.1."

It is the Examiner's position that the rejection stands until the rejected claims are cancelled or until a terminal disclaimer is filed. In addition, this is not the last remaining rejection. Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 36-43 and 66-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation of being a 'mutant bet v1 allergen derived from a naturally occurring bet v 1 allergen from the order Fagales' is unclear because it is impossible to distinguish between a mutant and a naturally occurring sequence until such a naturally occurring sequence becomes part of the art in the field.

The scope of the claims would be changeable as more wild-type allergen sequences are identified.

Correction is required.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 36, 38-43 and 66-73 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of a recombinant mutant allergen from birch pollen major allergen Bet v a of SEQ ID NO:37 having the amino acid substitutions recited in claim 37.

However, applicant is not in possession of: a recombinant mutant Bet v 1 allergen derived from a naturally-occurring Bet v 1 allergen from the order Fagales, said recombinant mutant Bet v 1 allergen having: (a) a substitution of **a solvent-accessible amino acid residue that is conserved among Bet v 1 homologous allergens within the order Fagales**, said substitution occurring in **a B-cell epitope of said naturally-occurring Bet v 1 allergen**; (b) reduced specific IgE binding compared to said naturally-occurring Bet v 1 allergen from which it is derived; and (c) **an α-carbon backbone tertiary structure that is preserved as compared to the α-carbon backbone tertiary structure of said naturally-occurring Bet v 1 allergen** of claim 36; wherein said **solvent accessible conserved amino acid residue has a solvent accessibility of at least 20%** of claim 38; wherein **said conserved solvent-accessible amino acid residue is conserved with more than 70% identity among Bet v 1 homologous allergens within the taxonomic order from which said naturally-occurring Bet v 1 allergen originates** of claim 39; wherein the specific IgE binding of said mutant Bet v 1 allergen compared to said naturally-occurring Bet v 1 allergen from which it is derived is reduced by at least 5% of claim 40; wherein **the average root mean square deviation of the atomic coordinates comparing the α-carbon backbone tertiary structures of said recombinant mutant Bet v 1 allergen and**

said naturally-occurring Bet v 1 allergens is less than 2 Å in claim 41; wherein **said conserved solvent-accessible amino acid residue is within a patch of conserved amino acid residues connected over at least 400 Å of the surface of said naturally-occurring Bet v 1 allergen**; wherein said **solvent-accessible amino acid residue that is conserved among Bet v 1 homologous allergens within the taxonomic order from which said naturally-occurring Bet v 1 allergen is substituted with an amino acid that is not conserved among Bet v 1 homologous allergens within the taxonomic order from which said naturally occurring Bet v 1 allergen occurs**; or a recombinant mutant allergen derived from a naturally-occurring allergen within the order Fagales that is **homologous to Bet v 1 allergen**, said recombinant mutant allergens having: (a) **a substitution of a solvent-accessible amino acid residue that is covered among homologous allergens within the taxonomic order Fagales**, said **substitution occurring in a B-cell epitope of said naturally-occurring allergen**; (b) reduced specific IgE binding compared to said naturally-occurring allergen; and (c) **an α-carbon backbone tertiary structure that is preserved as compared to the α-carbon backbone tertiary structure of said naturally-occurring allergen** of claim 66; wherein said allergens homologous to Bet v 1 have an amino sequence that yields a BLAST probability of less than .1 when compared to an amino acid sequence of SEQ ID NO:37 of claim 67; wherein **said solvent-accessible conserved amino acid residue has a solvent accessibility of at least 20%** of claim 68; wherein **said conserved solvent-accessible amino acid residue is conserved with more than 70% identity among homologous allergens within the taxonomic order from which said naturally-occurring allergen originates** of claim 69; wherein the specific IgE binding of said mutant allergen compared to said naturally occurring allergen from which it is derived is reduced by at least 5%

of claim 70; wherein **the average root mean square deviation of the atomic coordinates comparing the α-carbon backbone tertiary structures of said recombinant mutant allergens and said naturally-occurring allergen is less than 2 Å** of claim 71; wherein **said conserved solvent-accessible amino acid residue is within a patch of conserved amino acid residues connected over at least 400 $Å^2$ of the surface of said naturally-occurring allergen** of claim 72; or wherein **said solvent-accessible amino acid residue that is conserved among homologous allergens within the taxonomic order from which said naturally-occurring allergen occurs** for the same reasons as set forth in the Office Action mailed on 05/22/2009.

Applicant's arguments submitted on 06/21/2010 have been fully considered, but are not found persuasive.

Applicant argues:

"Applicants' previously-filed amendments and responses have outlined in detail the reasons why the specification provides written description for the claimed invention. *See,* e.g., responses filed April 30, 2008 and February 6, 2009.

Thus, it was general knowledge in the art at the time the application was filed that allergens with reduced IgE binding could be produced by site-directed mutagenesis. *See* specification and cited references at page 7, line 26, et seq. The specification further discloses that the amino acids available for antibody binding are located on the surface of allergens *(see* specification at page 19, lines 30-36). The functional characteristic of reduced IgE binding flows directly from (i.e., is "coupled with") the known property of IgE epitopes to be present on the surface of allergens, particularly in conserved patches on the allergen surface, and the disclosed and well known correlation that disrupting IgE epitopes will reduce IgE binding. The state of the art was such that it was known, for example, that Bet v 1 allergens include IgE epitopes, that they reside in surface patches, that Bet v 1 proteins from the order Fagales share a high level of identity and exhibit cross reactivity, and that substitution of amino acids on the surface of Bet v 1 allergens could disrupt IgE epitopes and lower IgE binding.

The specification sets forth that: The major birch pollen allergen Bet v 1 (SEQ ID NO: 37) shows about 90% amino acid sequence identity with major allergens from pollens of taxonomically related trees, i.e. *Fagales* (or instance hazel and hornbeam) and birch pollen allergic patients often show clinical symptoms of allergic cross-reactivity towards these Bet v 1 homologous proteins.

Specification at page 24, lines 8-14. Based on the level of skill in the art at the time the application was filed, a worker of ordinary skill in the art would have recognized that the high degree of identity among Bet v 1 homologous proteins from the order Fagales and the finding that birch pollen allergic patients exhibited symptoms of allergic cross-reactivity towards these homologous proteins indicates that Bet v 1 homologous proteins from the order Fagales have highly similar primary sequences and three-dimensional structures, indicating that the features that are set forth above and which indicate that the Applicants had possession of the mutant allergens for Bet v 1 proteins from the order Fagales also hold for the broader genus of recombinant mutant allergens of Bet v 1 homologous proteins from the order Fagales. Thus, the specification provides written description for the full scope of recombinant mutant Bet v 1 allergens from the order Fagales. *See* claims 36 and 66.

The specification read in light of the knowledge of the state of the art also provides written description for each of the particular features recited the claims. Thus, the general level of skill and knowledge in the art would readily allow one of ordinary skill in the art to use the known crystal structure of Bet v 1 and/or sequence alignment of Bet v 1 sequences to identify amino acids that have a solvent accessibility of 20% (claims 38 and 68), identify amino acids that are conserved with 70% identity among Bet v 1 allergens from the order Fagales (claims 39 and 69), wherein a conserved solvent-accessible amino acid residue is within a patch of conserved amino acid residues connected over at least 400.A_ of the surface of said naturally-occurring Bet v 1 allergen (claims 42 and 72), wherein the solvent-accessible amino acid residue that is conserved among Bet v 1 homologous allergens within the taxonomic order from which said naturally-occurring Bet v 1 allergen is substituted with an amino acid that is not conserved among Bet v 1 homologous allergens within the taxonomic order from which said naturally- occurring Bet v 1 allergen occurs (claims 43 and 73) and wherein said allergens homologous to Bet v 1 have an amino sequence that yields a BLAST probability of less than 0.1 when compared to an amino acid sequence ofSEQ ID NO: 37 (claim 67). The specification further provides extensive guidance on tests that can be used to determine with recombinant Bet v 1 allergens have IgE binding reduced by at least 5%, compared to the naturally-occurring Bet v 1 allergen from which it is derived (claims 40 and 70) and wherein average root mean square deviation of the atomic coordinates comparing the a-carbon backbone tertiary structures of said recombinant mutant Bet v 1 allergen and said naturally-occurring Bet v 1 allergen is less than 2A (claims 41 and 71).

Thus, the Applicants were in possession of the complete subject matter of claims 36, 38-43 and 66-72.

In short, the structure of Bet v 1 was known at the time the application was filed and Bet v 1 allergens are highly conserved. There is no rule that the Applicants provide description of the precise mutant amino acids in the claimed recombinant Bet v 1 mutants. *Falkner v. Inglis,* 448 F.3d 1357, 1366 (Fed. Cir. 2006). Applicants are entitled to "flexibility" in how they claim their invention. *Univ. of Rochester v. G.D. Searle & Co., Inc.,* 358 F.3d 916, 927-928 (Fed. Cir. 2004). In *Ariad v, Eli Lilly, the* Federal Circuit reiterated, "[written description] doctrine never created a heightened requirement to provide a nucleotide-by- nucleotide recitation of the entire genus of claimed genetic material; it has always expressly permitted the disclosure of structural features common to the members of the genus." *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.,* cv 2008-1248, Fed. Cir., *en banc,* decided March 22, 2010, slip op at 26, *citations omitted.* Here, the claims call for "a substitution of a solvent- accessible amino acid residue that is conserved among *Bet v I* homologous allergens within the taxonomic order *Fagales,* said substitution occurring in a B-cell epitope of said naturally- occurring *Bet v I* allergen" *(see* claim 36) or "a substitution of a solvent-accessible amino acid residue that is conserved among homologous allergens within the taxonomic order *Fagales,* said substitution occurring in a B-cell epitope of said naturally-occurring allergen,' *(see* claim 66), where the substitution leads to reduced IgE binding. When measured against the known, conserved structure of Bet v 1 allergens and the high level of skill in the art concerning B-cell epitopes, the claims tell one of ordinary skill in the art where mutations are placed in the claimed recombinant allergens. The claims thus describe the claimed invention and do not "merely [draw] a fence around the outer limits of a purported genus." *Id.* at 21."

Applicant argues that the instant applications identifies numerous amino acid for substitution in Fagales group 1 allergens and further sets forth examples of combinations of mutants. However, given that Applicant is not in possession of the genus of fagales Group I allergens to be modified, Applicant is accordingly not in possession of the genus of mutants that can be made to a genus of allergens that they do not and cannot possess. Applicants have no way of knowing how to modify as yet undiscovered allergens that may differ from known allergens in ways that cannot be contemplated.

As stated supra, in the 112, second paragraph rejection, the limitation of being a 'recombinant mutant Bet v1 allergen derived from a naturally-occurring Bet v1 allergen from the order Fagales' is not adequately described because it is impossible to distinguish between a mutant and a naturally occurring sequence until such a naturally occurring sequence becomes part of the art in the field. The scope would be changeable as more wild-type allergen sequences are identified.

Applicant argues that the instant specification sets out the features, including specific amino acids, of Fagales group 1 allergens that are called for in the claims and which allow one of ordinary skill in the mutant art to make the claimed recombinant allergens. What one of ordinary skill in the art could do with time and experimentation is not at issue here. What is at issue here is whether Applicant is in possession of their claimed invention. There is no way to know what is or is not an allergen that is encompassed by the scope of the claims given the information disclosed in the specification. The specification has not adequately disclosed a correlation between the amino acid structure of the genus of all of the mutant allergens

encompassed and the function of exhibiting reduced IgE binding. There is no way to know what is encompassed by the term "recombinant mutant Bet v1 allergen derived from a naturally-occurring Bet v1 allergen from the order Fagales" and whether a particular residue is conserved among all homologous allergens. If one were to later discover a homologous allergen with a previously undiscovered amino acid in a previously undiscovered isoform of one of the recited allergens in one of the recited positions would that naturally occurring sequence be a mutant of a naturally occurring sequence? One of ordinary skill in the art would not be able to determine what is encompassed by the instantly recited recombinant mutant allergen of a naturally occurring allergen. The issue is much greater when you factor in unknown isoforms.

It remains the Examiner's position that the specification has not adequately described the genus of allergen mutants encompassed by the instant claim recitations. Again, it remains the Examiner's position that the specification does not disclose a correlation between structure of the allergen and function (reduced specific IgE binding) and in this case functional limitations ("occurring in a B-cell epitope" and "α-carbon backbone tertiary structure that is preserved" of claim 36 "wherein said solvent accessible conserved amino acid residue has a solvent accessibility of at least 20%" of claim 38; "wherein the specific IgE binding of said mutant Bet v 1 allergen compared to said naturally-occurring Bet v 1 allergen from which it is derived is reduced by at least 5%" of claim 40; "wherein the average root mean square deviation of the atomic coordinates comparing the α-carbon backbone tertiary structures of said recombinant mutant Bet v 1 allergen and said naturally-occurring Bet v 1 allergens is less than 2 Å" in claim 41; "wherein said conserved solvent-accessible amino acid residue is within a patch of conserved amino acid residues connected over at least 400 Å of the surface of said naturally-occurring Bet

v 1 allergen" of claim 42; "an amino sequence that yields a BLAST probability of less than .1 when compared to an amino acid sequence of SEQ ID NO:37" of claim 67; "wherein said solvent-accessible conserved amino acid residue has a solvent accessibility of at least 20%" of claim 68; "wherein the specific IgE binding of said mutant allergen compared to said naturally occurring allergen from which it is derived is reduced by at least 5%" of claim 70; "wherein the average root mean square deviation of the atomic coordinates comparing the α-carbon backbone tertiary structures of said recombinant mutant allergens and said naturally-occurring allergen is less than 2 Å" of claim 71; "wherein said conserved solvent-accessible amino acid residue is within a patch of conserved amino acid residues connected over at least 400 $Å^2$ of the surface of said naturally-occurring allergen" of claim 72) such that a skilled artisan would have known what modification to make to the Bet v 1 allergens to attain the claimed function and functional limitations. "Possession may not be shown by merely describing how to obtain possession of member of the claimed genus or how to identify their common structural features" In re Kubin, of record, at page 16. In this instant case Applicants have not provided sufficient guidance as to what mutation or combination of mutations will result in the claimed functions and functional limitations. "Without a correlation between structure and function, the claim does little more than define the claimed invention by function" *supra*, at page 17.

Applicant is claiming allergen mutants with functional characteristics which are not well known in the art and allergen mutants wherein the mutations are made to amino acid residues of "homologous" allergens. One of ordinary skill in the art might be able to experimentally figure out the genus, but that does not change the fact that Applicant has not adequately described them.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 36 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman-Sommergruber et al. (PTO-892; Reference U).

Hoffman-Sommergruber teaches wild type Bet v 1 major birch pollen allergen Hoffman-Sommergruber teaches naturally occurring Bet v 1 clone 'bvg63' corresponding to GenBank/EMBL database accession No. Z72435 by name on page 93, 'betv1 genes' section lines 4-6 and 29 with a sequence that is 85.5% identical to SEQ ID NO:69 with the following mutations: H76R (Group 7); T94A (Group 9); T107A (Group 4) and A135I (Group 1).

Hoffman-Sommergruber teaches wild type Cor a1 clone 'cagc10' corresponding to GenBank/EMBL database accession No. Z72439 with a sequence that is 85.5% identical to SEQ ID NO:69 with the following mutations: D27N (Group 3); T94K (Group 9); T107A (Group 4) and A135G (Group 1) and S149A (Group 5). (In particular, Figure 2)

The recitation of 'a mutant bet v 1 allergen derived from a naturally occurring Bet v 1 allergen' is encompassed by the wild type sequences of Hoffman-Sommergruber because the specification does not provide a limiting definition for the phrase.

The recitation of "wherein the specific IgE binding compared to said naturally occurring Bet v 1 allergen from which it is derived" in claim 36; and "reduced specific IgE binding compared to said naturally occurring allergen" in claim 66 are inherent in the reference allergens. Products of identical chemical composition cannot have mutually exclusive properties because a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

The reference teachings anticipate the claimed invention.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-

0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 30, 2010

/Nora M Rooney/

Primary Examiner, Art Unit 1644